
Urgent Field Safety Notice

**PediNail 4.5mm X 48mm Cortical Screw
CM16-508
Field Safety Corrective Action**

Date:

Attention: ////////////////

Details on affected devices:

Part Number	Lot Number	Description
10-1500-3048	161412-G	4.5mm X 48mm Cortical Screw

Description of the problem:

The purpose of this Field Safety Notice is to advise you that OrthoPediatrics has initiated a Field Safety Corrective Action on the PediNail 4.5mm X 48mm Cortical Screw listed above. This is based upon OrthoPediatrics' determination that these screws are labelled and etched incorrectly. The screw is measuring at 50mm when they should be measuring at the 48mm.

Advise on action to be taken by the user:

- Please immediately take possession of any of these screws your customer may have or that you have, and quarantine them. Contact logistics@orthopediatrics.com to receive a Return Authorization Number. It is very important that we contain these devices rapidly and maintain them in quarantine. Replacement devices can be ordered from Customer Service.
- The FedEx package you receive will contain a pre-addressed FedEx return label for the return of the recalled screw(s).
- Included in this FedEx package is a Mandatory Reply Form for you to indicate the total number of affected screw(s) in your sets.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Adam S. Cargill, Regulatory Affairs Associate Manager
Phone: (574) 268-6379
Fax: (574) 269-3692
E-mail: acargill@orthopediatrics.com

We are proactively addressing this issue by initiating this Field Safety Corrective Action, which elevates this to a top priority for our team. We regret any inconvenience this matter may have caused. We sincerely appreciate your cooperation and thank you for your assistance on this issue to protect our kids.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

Signature